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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,122	08/22/2003	Nagi M. Awad	119.002	8854

7590 07/30/2004

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EXAMINER	
ZIMMER, MARC S	

ART UNIT	PAPER NUMBER
1712	

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,122	AWAD, NAGI M.	
	Examiner	Art Unit	
	Marc S. Zimmer	1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Examiner sent out a first Office action on the merits on July 24, 2004 but failed to fully consider the impact of Applicant's statements concerning the on-sale activity of a similar product. The findings associated with this disclosure are set forth herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 and 17-33 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. Applicant has provided a history of on-sale activity for a hydrosilylation-cured silicone gel that is derived from one of a divinyl-terminated polydimethylsiloxane or a divinyl-terminated polydiphenyldimethylsiloxane copolymer, a methylhydrogensiloxane, and one of several low molecular weight/viscosity siloxane fluids or hydrocarbon oils. It is acknowledged that these components are not described in sufficient detail so as to ascertain that they meet all of the structural limitations outlined in claim 1.

Nonetheless, Applicant's mention of these formulations and their availability more than one year prior to the filing date of the provisional would seem to be an admission that they mirror the instantly claimed gels in their chemical makeup. It is notable, for instance, that Applicant's description of the sales activity surrounding Formulation C includes two quotes for a product, one of which was given more than one year prior to

the filing of a provisional application and the other of which was offered for sale less than one year before the effective date of said provisional application. By all appearances, the only difference between the products quoted before- and after the date that represents one year before the provisional filing is the mode of preparation. In particular, the gel quoted on the later date was prepared under conditions of controlled shear whereas the other was manufactured under conditions wherein the shear was not regulated. However, it is noted that every claim with the exception of claim 16 is devoid of any indication that shearing was controlled during the gel's preparation. It is, therefore, assumed for the purpose of this rejection that the sales activity delineated as part of Applicant's Information Disclosure Statement represents an on-sale bar of each of the product claims.

It is, likewise, assumed that all of the process limitations set forth in claims 7-15 and 17-18 are followed in the preparation of the formulations because, again, Applicant seems to distinguish the formulations made available more than one year before the provisional application from those made available less than one year before the provisional application, which apparently are embodiments of the claimed invention, only by the utilization of controlled shear during the course of gel formation. Indeed, it is presumed that all aspects of the claimed invention, including the intended use and methods of use, were known more than one year prior to the effective date of the provisional application with the exception of the aspect of controlled shear employed during the manufacturing process as this feature is emphasized repeatedly in the history of sales activity and in the Specification at paragraphs 23 and 24.

The following is a restatement of the claim objections and rejections administered in the correspondence dated July 24, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Shearing and mixing are conceptually analogous in that shearing is a form of mixing that generally employs some mechanical means to promote the movement of materials. In this sense, claim 16 is in direct conflict with claim 8 and the disclosure at paragraph 23 as claim 8 discloses mixing until the gelling is discernable and paragraph 23 states that mixing is done with a small blade. Therefore, not all of the polymerization is performed in the absence of shearing forces.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what precisely is meant by "milled in the swollen stage". Two possible meanings are immediately surmised: (i) milling is carried out thereby bringing about swelling of the gel or (ii) milling of the gel in its swollen *state* is carried out. Based on the Specification, it appears that the latter is true but clarification is needed. For the purpose of evaluating these claims against the prior art, it is assumed that either statement is true.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-6, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuwata et al., U.S. patent # 4,987,169. Kuwata discloses a crosslinked silicone product that may be employed as a thickening agent for silicone oils that are often employed in the formulation of cosmetics (column 2, lines 25-31). The crosslinked product is derived from a mixture of an organohydrogensiloxane characterized in column 3, lines 43-67 through column 4, lines 1-11 and an alkenyl group-functionalized polysiloxane fitting the description offered in column 4, lines 12-39. The reaction between these materials is carried out in the presence of a low viscosity silicone oil such as those mentioned in column 5, lines 20-28. According to column 5,

lines 29-38, the silicone oil is preferably made available as 20 to 500 parts by weight relative to 100 parts by weight of the crosslinked product precursors. Notably, where the oil is added as better than 425 weight parts the limitation of claim 4 is satisfied. Relevant to the claimed structural limitations of the gel-forming materials, the organohydrogensiloxane is, in a preferred embodiment (Example 1) a linear polysiloxane having trimethylsilyl terminal groups, dimethylsiloxane repeat units, and methylhydrogensiloxane repeat units. The alkenyl group-functionalized polymer is dimethylvinyl-terminated polydimethylsiloxane.

On the other hand, the molecular weights provided for these specific embodiments, do not adhere to the molecular weight requirements of components (A) and (B) of claim 1. Nonetheless, column 4, lines 13-21 states that variable (g), which corresponds to "n" of component (B) of the claimed invention may equal 0 to 500. Likewise, column 3, lines 43-51 contemplate an organohydrogensiloxane wherein variable (c) corresponding to "p" of the instant invention is 0 to 500 and (d) corresponding to "q" of the instant invention is 0 to 50. The fact that (i) these ranges fully encompasses the claimed ranges and, in the Examiner's view, do so with specific specificity coupled with (ii) Applicant's failure to demonstrate criticality for the claimed ranges renders these aspects of the claimed invention obvious. "A prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson* 315 F.3d 1325, 1330, 56USPQ2d 1379, 1382-83 (Fed Cir. 2003).

As for claim 6, equivalent gels, their dilution with a low-viscosity silicone oil, and their utilization in the formulation of cosmetics are all contemplated. Cosmetically acceptable ingredients are not expressly mentioned but the skilled artisan will appreciate that these adjuvants are to be combined with the gel whenever it is employed in cosmetics production. The amounts of the gel, diluent, and cosmetically, acceptable ingredients are also not contemplated but ready determination of these parameters is not beyond the capabilities of one having ordinary skill. "Discovering an optimum value of a result effective variable involves only routine skill in the art." *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

As for claim 33, it is noted that Applicant has not identified a single material that is envisioned to be "suitable for application to rubber or rubber-like surfaces. This is significant because it represents, in the Examiner's view, an admission that thes materials are known to the skilled artisan. While the reference does not contemplate applying their gel to the surface of a rubber article, it is considered that said gel maybe incorporated into a rubber (column 2, lines 35-37). In doing so, it is inherently combined with other materials that are suitable for the rubber.

Concerning claims 2, 3, 7, 9-10, 12-15, 17-22, 24-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuwata et al., U.S. patent # 4,987,169 in view of the dictionary definition of "mill" taken from Merriam-Webster's Dictionary. Concerning claim 7, the reference teaches the preparation of a paste or grease derived from an equivalent gel at column 6, lines 31-68 through column 7, lines 1-32. The process entails polymerization of structurally equivalent organosilicon starting materials

in the presence of a platinum hydrosilylation catalyst and the low viscosity silicone oil at 50-150° C. Thereafter, it is stated that the resulting powder is subjected to a shearing force that results in the powder being further ground but "milling" of said powder is never expressly mentioned. However, "mill", according to Merriam Webster's Dictionary, may refer to a machine for crushing or comminuting. By extension, "milling" would refer to the act of crushing or comminuting, which are synonomous with "grinding". That is, although the reference does not disclosing sending the powder through a milling device per se, said powder is, nonetheless, ground or milled by the applied shearing forces. On the other hand, the reference teaches the subsequent treatment of the powder with more of the low-viscosity silicone under shearing forces. Shearing in this instance is carried out in, among other devices, a colloid mill. It seems unlikely that the shearing devices outlined in column 7, lines 26-29 are for the second shearing operation exclusively but, ultimately, the exact intentions of the reference cannot be ascertained. It is, nevertheless, the Examiner's contention that one of ordinary skill would infer from the reference that the first milling operation could also be performed with the same apparatus hence claims 3 and 9 are also rejected.

As for claim 13, the polymerization reaction is carried out for two hours in the particular embodiment recited in Example 1. Claims 14 and 15 are rejected because, though a polymerization time of only two hours is disclosed by way of Example, this should not be taken as an express limit on the recommended polymerization duration. Indeed, the reference does not provide any suggestion of a range of polymerization

times. This omission notwithstanding, the skilled artisan can determine the required polymerization time as a matter of routine experimentation.

Claims 19-27 are clearly obvious in view of the previous discussion.

As for claims 28 and 29, the gels and the paste/grease derived therefrom, are characterized as being transparent in column 2, lines 28-47.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuwata et al., U.S. patent # 4,987,169 in view of Karstedt et al., U.S. Patent # 3,775,442. Kuwata et al. identify the catalysts of Karstedt as appropriate for use in their invention. These catalysts according to the supporting reference are divinylsiloxane complexe4s of platinum.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc S. Zimmer whose telephone number is 571-272-1096. The examiner can normally be reached on Monday-Friday 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 27, 2004

Marc Zimmer

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AU 1712